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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,781	01/09/2002	Joseph J. Florio	A02P1001	1563
36802	7590	03/01/2005	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER

3762

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/043,781	<b>Applicant(s)</b> FLORIO ET AL.	
	<b>Examiner</b> Kennedy Schaetzle	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-6, 8-13 and 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Florio et al. (Pat. No. 6,519,493).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claim 1 and claims with similar limitations, Florio et al. disclose an overdrive pacing method comprising inputting an initial shape for an overdrive pacing response function for use in overdriving the heart (note Fig. 5 and steps 400-403), controlling the pulse generator to overdrive pace the heart at an overdrive pacing rate specified by the shape of the overdrive pacing response function (step 403), determining whether the degree of overdrive pacing achieved using the overdrive pacing response function falls below a threshold (steps 404, 406 and 408; also note col. 9, lines 44-65), and adjusting the shape of the overdrive pacing response function so as to improve the degree of overdrive pacing to be achieved during further overdrive pacing if the degree of overdrive pacing falls below the threshold (step 412).

Although Florio et al. do not explicitly refer to a "shape of the response function" *per se*, all functions relating the heart rate to the overdrive pacing rate have a characteristic shape describing them (e.g., such as shown in the present invention's

prior art Fig. 1). Florio et al. further state that various parameters such as the overdrive pacing margin may be dynamically adjusted in a non-linear manner (note the text abridging cols. 9 and 10). Non-linear adjustments are considered to inherently change the shape of the overdrive pacing response function.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over Florio et al. (Pat. No. 6,519,493).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Florio et al. do not appear to discuss the length of the heart rate tracking period. Those of ordinary skill in the art, however, would have considered the setting of this period to be a proverbial judgment-call and thus a matter of obvious design. Routine experimentation to ascertain the most effective time period to ensure optimized pacing, while at the same time limiting excessive battery depletion and unnecessary and frivolous adjustment would factor into this decision. The applicants further express no criticality in the exact timing of this period, further supporting the above assertion.

Regarding claim 14, while Florio et al. do not discuss the use of interpolation to ascertain overdrive pacing rates between specified breakpoints, the examiner takes Official Notice that it is old and well-known to mathematically determine values on a segmented curve by utilizing two points and interpolating to obtain a third point using the equation of the line between the two points. Such a system simplifies matters by not requiring all points on a curve to be stored in a look-up table when attempting to determine the corresponding overdrive pacing rate for the particular heart rate detected. Only the points where the curve changes slope need be stored to describe all points on the curve. To utilize interpolation between breakpoints in the device of Florio et al. would have therefore been considered obvious to those of ordinary skill in the art.

### ***Response to Arguments***

5. Applicant's arguments filed December 29, 2004 have been fully considered but they are not persuasive.

Applicants' argue that the Florio et al. reference does not disclose or suggest adjusting the shape of the overdrive pacing response function to improve the degree of overdrive pacing to be achieved during further overdrive pacing, and further go on to cite an example of how the Florio et al. device operates (contrary to the applicants' comment on page 3 of the Remarks, the examiner did not state that Florio et al. do not disclose or suggest adjusting the shape of the overdrive pacing response function – merely that Florio et al. did not *explicitly* refer to a shape adjustment). While the examiner understands how the Florio et al. device works with regards to the linear embodiment discussed in the Remarks, the applicants did not address the non-linear

embodiment relied upon by the examiner as discussed in the first full paragraph of page 3 of the previous Office Action. In this embodiment, the change may be of a non-linear nature. An adaptive non-linear change or a change from linear to non-linear operation (note the text abridging cols. 9 and 10) results in a change of shape. The applicants, in fact, refer to non-linear changes on page 10 of the present specification (see also Figs. 1 and 7). Furthermore, nothing in the claim precludes one from periodically adjusting or tweaking the shape in follow-up visits by changing the programming from a linear adjustment regimen to a non-linear adjustment regimen and vice versa (or simply making the non-linear overdrive response more or less aggressive). The device of Florio et al. allows for linear and non-linear adjustments depending upon the particular programmable values and the amount of difference between the actual degree of pacing and the target degree of pacing. Programmable values such as the overdrive pacing margin may be adaptively adjusted.

Finally, statements of intended use (i.e., adjusting the shape so as to improve the degree of overdrive pacing to be achieved during further overdrive pacing if the degree of overdrive pacing falls below the threshold) are considered insufficient to saliently distinguish over the method of Florio et al.. By analogy, one could claim a method comprising the step of turning on an oven so as to bake a cake, but this does not limit the method to cake baking. A reference disclosing the step of turning on an oven to heat a room would also read on this type of claim.

Based upon the above arguments and the applicants' comments, the rejection must stand.

### ***Conclusion***

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 3762


extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached M-W and F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached M-F at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS  
February 25, 2005



KENNEDY SCHAETZLE  
PRIMARY EXAMINER